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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/622,353	09/12/2000	John A. Arbuckle	0457-PCT-US	4766

7590

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EXAMINER

TUNG, JOYCE

ART UNIT	PAPER NUMBER
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1637

DATE MAILED: 07/05/2002

13

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/622,353

Applicant(s)

ARBUCKLE ET AL.

Examiner

Joyce Tung

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 18 April 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: *Detailed Action*.

Art Unit: 1637

### **DETAILED ACTION**

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1637.

#### ***Request for Continued Examination***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/18/2002 has been entered.
2. The amendment filed 4/18/2002 has been entered.
3. Applicant's arguments with respect to the rejections of claims 1-21 have been considered but are moot in view of the new ground(s) of rejection.

#### ***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Art Unit: 1637

5. Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claim 2 is vague and indefinite because of the language "an amplification product". It is unclear whether the amplification product is referred from the amplification product from step e of claim 1. Clarification is required.

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Art Unit: 1637

7. Claims 1, 4-7, 9-13, and 15-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Briggs et al. (5,962,764) in view of Lindemann et al. (5,958,738).

Briggs et al. disclose a method for determining the function of a gene involving using the highly active Mutator family of transposable elements as a means of minimizing the number of F1 plants required to ensure a desired insertion event (See column 4, lines 22-26). Most transposable elements carry terminal inverted repeat (TIR) sequences located at each terminus of the transposable element but inverted with respect to each other (See column 4, lines 61-65). Genomic DNA isolated from the F1 plants is used as target within a gene of known sequence is detected by using one primer complementary to the gene of interest, and in a preferred embodiment, one primer complementary to the terminal inverted repeat sequence of the transposable element is used for the detection (See column 6, lines 7-13). This suggests that primer is a Mutator-TIR primer derived from the TIR sequence (as recited in claims 6).

The method of Briggs et al. do not disclose the method steps as recited in claim 1 and the method will be used for identifying the location of the insertions by a transgene in genomic DNA as recited in the preamble of claim 15. However, Brigg et al. indicate that by observation of a discrete PCR product in the gel, an insertion event has occurred within or close to the gene of interest. Confirmation of an insertion occurred within a gene or specific segment of a gene, rather than outside can be obtained by repeating the PCR using additional gene-specific primers together with primers complementary to the transposable element. This allows the site of the insertion to be estimated (See column 8, lines 9-22).

Art Unit: 1637

Lindemann et al. disclose the improved method for obtaining polynucleotides comprising sequences which differ between two populations of DNA (See the Abstract) involving two polynucleotide populations fragmented (as recited in claims 1, 15, and 20) which are attached an oligonucleotide comprising nested primer binding sites or the complements thereof in which the primer binding sites comprising an outermost primer binding site, an innermost primer binding site and at least one more internal primer binding site between to produce marked sample and control sample (See column 10, lines 26-48). The teachings of Lindemann et al. suggest that the primer is nested as recited in step (e) of claim 1 and step (d) of claim 15 and the oligonucleotide of Lindemann et al. has the same function as the recited adapter in steps (d)-(e) of claim 1 and steps (c)-(d) of claim 15 and claim 10

In addition, Lindemann et al. disclose that the method is for the identification and isolation of polynucleotides comprising nucleic acid sequences present in a first (sample) cell, cell type, or cell population that are not present in one or more other cells or cell populations. Such polynucleotide is identified as "unique fragments" which may be obtained as a results of differences in sequence content, such as insertion or deletion (See column 5, lines 60-67 to column 6, lines 1-3).

Thus, it would have been prima facie obvious to an ordinary skill in the art at the time of the instant invention to combine the teaching of Brigg et al. and Lindemann et al. to make the instant invention as claimed with a reasonable expectations of success. The motivation is that The method of Briggs et al. is a rapid, inexpensive method for determining the function of a

Art Unit: 1637

gene of known sequence (See column 3, lines 15-19) involving a primer complementary to the TIP sequence of the transposable element (See column 6, lines 7-13) and the method of Lindemann et al. overcomes the disadvantage by using fewer PCR cycles, nuclease digestion before amplification and a single adapter designed for use with multiple primers (See column 5, lines 52-55). Therefore, an ordinary skill in the art at the time of the instant invention would have been motivated to combine the teachings of Brigg et al. and Lindemann et al. to carry out the method as claimed.

8. Claims 2 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Briggs et al. (5,962,764) in view of Lindemann et al. (5,958,738) as applied to claims 1, 4-7, 9-13, and 15-21 above, and further in view of Schunable et al. (5,684,242).

The teachings of Briggs et al. and Lindemann et al. do not disclose using cosegregation analysis to isolate DNA amplification product that cosegregates with the mutant phenotype.

Schunable et al. disclose a method for the production of hybrid seed (See column 5, lines 31-39). The plant used is from maize (See column 8, lines 55-58) as recited in claim 8. Cosegregation analysis was performed to isolate the DNA amplified product that cosegregates with the mutant phenotype (See column 19, lines 33-43).

One of ordinary skill in the art would have been motivated to combine the teachings of Brigg et al., Lindemann et al. and Schunable et al. to make the instant invention with a reasonable expectation of success. Regarding the motivation of combining the teachings of Brigg et al. and Lindemann et al. it was set forth in section 7 above, and the method of

Art Unit: 1637

Schunable et al. involved using cosegregation analysis in which the location of insertion is clearly marked (See column 20, lines 14-16). Thus, it would have been prima facie obvious to carry out the method as claimed.

9. Claims 3 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Briggs et al. (5,962,764) in view of Lindemann et al. (5,958,738) as applied to claims 1, 4-7, 9-13, and 15-21 above, and further in view of Halverson et al. (5,707,809).

The teachings of Briggs et al and Lindemann et al. are set forth in section 7 above and do not teach using bulked segregant analysis to isolate the amplified products as claimed in claim 3 and labeled primer as claimed in claim 14.

Halverson et al. disclose a method for sex identification involving bulked segregant analysis (See column 21, lines 23-26) and that the primer used is joined to a label (See column 38, lines 23-25).

One of ordinary skill in the art at the time of the instant invention would have been motivated to combine the teachings Brigg et al, Lindemann et al., and Halverson et al. to make instant invention with a reasonable expectation of success because of the motivation of combining the teachings of Brigg et al. and Lindemann et al., discussed in section 7 above and in addition the method of Halverson et al. is simple, accurate and efficient (See column 25, lines 17-20). It would have been prima facie obvious to carry out the method as claimed.

Art Unit: 1637

10. Any inquiries concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (703) 305-7112. The examiner can normally be reached on Monday-Friday from 8:00 AM-4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at (703) 308-1119 on Monday-Friday from 10:00 AM-6:00 PM.

Any inquiries of a general nature or relating to the status of this application should be directed to the Chemical/Matrix receptionist whose telephone number is (703) 308-0196.

11. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Art Unit 1637 via the PTO Fax Center located in Crystal Mall 1 using (703) 305-3014 or 308-4242. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Joyce Tung

June 28, 2002

  
GARY BENZION, Ph.D.  
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